DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-255/S-008

Baxter Healthcare Corporation
Attention: Ms. Marcia Marconi
Route 120 & Wilson Road
RLT-10
Round Lake, IL 60073-0490

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated May 11, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dobutamine HCl 5% Dextrose Injection, USP in Viaflex Plastic Container.

We acknowledge receipt of your submission dated March 30, 2001 that constitutes a complete response to our January 3, 2001 approvable letter.

This supplemental new drug application provides for final printed labeling revised as follows:

1. Under **Precautions,** a **Geriatric Use** subsection has been established and reads as follows:

   Clinical studies of dobutamine injection did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

2. Under **Description**, the 5th and 6th sentences of the last paragraph have been changed to:

   Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however biological testing was supportive of the safety of the plastic container materials.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your submission of March 30, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5313

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research